TEXAS
PHARMACY
ASSOCIATION

May 18, 1999

Dockets Management Branch
Food and Drug Administration
(HFA-305), Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Docket Number 98N-1265
Federal/State Memorandum of Understanding on Interstate Distribution of Compounded Drug Products

To Whom It May Concern:

The Texas Pharmacy Association Section of Compounding Pharmacists (SCmP) submits the following comments in response to the Food and Drug Administration's (FDA's) request for comments on its draft Federal/State Memorandum of Understanding (MOU) on Interstate Distribution of Compounded Drug Products 64 Fed. Reg. 3301 (Jan. 21, 1999).

It is the consensus of SCmP member pharmacists that the arbitrary imposition of any limitation on the percentage of compounded prescriptions that may be shipped interstate will not reflect the intent of Congress in the enactment of the Food and Drug Administration Modernization Act (FDAMA). The professional decision that a compounded prescription is required for maximum therapy outcomes for a patient is entrusted to physicians based on the pharmacist-patient-practitioner triad. Arbitrary "ceilings" on the amount of prescriptions that may be compounded is unnecessarily disruptive to the practice of medicine and can only jeopardize the quality of patient care. Nothing in Section 503A or the legislative history suggests that Congress intended that FDA should impose a specific ceiling on the amount of compounded drugs that can be shipped interstate under the MOU. Since Congress did not impose a standard ceiling in the text of 503A, it is SCmP's contention that such a ceiling as proposed by the MOU is unwarranted. While Congress set five percent as a default ceiling, this does not imply that a ceiling is required at all, because Congress made no finding that the shipment of any percentage was "inordinate." FDA should determine that even the shipment of 100 percent of compounded prescriptions out-of-state is not "inordinate," provided that all of the other requirements in 503A (i.e., pharmacist-patient-practitioner triad) are met. Moreover, the specific ceilings selected by FDA are arbitrary and unconstitutional, bearing no rational relationship to the practice of medicine or pharmacy and the welfare of the patient in need of a compounded prescription.

In the state of Texas, many pharmacies now specialize in providing compounded prescriptions as their only commerce. Therefore, these compounding pharmacists oftentimes have interstate patients that have been referred to their practice by an attending physician. By arbitrarily limiting the interstate distribution of compounded prescriptions, FDA will force these pharmacists to ration

1624 East Anderson Lane, Austin, Texas 78752-1806 • P.O. Box 14709, Austin, Texas 78761-4709 • (512) 836-8350 • (800) 505-5463 • Fax: (512) 836-0308

their out-of-state shipments. How shall a small compounding pharmacy that has a unique ability to prepare a customized prescription decide which few out-of-state patients shall receive the therapy prescribed by the attending physician? As currently drafted, the MOU will force patients to get their compounded prescriptions filled from intrastate pharmacies than my be less experienced in compounding prescriptions, or have less skill in compounding a particular medication formula, rather than a more experienced out-of-state compounding pharmacy.

The SCmP member pharmacists also oppose the FDA's proposal to allow pharmacies to exclude prescriptions dispensed within a 50-mile radius from the ceiling calculations. Pharmacies located near state borders are likely to have disproportionately larger percentages of prescriptions that enter interstate commerce. As a result, the ceilings will have a greater economic impact on those pharmacies. Moreover, FDA's 50-mile exclusion, no matter how well intentioned, serves only to exacerbate the disparate impact of the MOU on compounding pharmacies. Pharmacies located in the Texas coastal area, such as Corpus Christi, could lose as much as 50 percent of the intended benefit of the exclusion calculation if half of the 50-mile radius includes coastal waters. Pharmacies located 51 miles from the state boarder will not benefit from the 50-mile exclusion at all, while pharmacies on the border will be able to exclude an interstate shipping area of several thousand square miles.

In conclusion, the SCmP member pharmacists cannot agree with FDA's idea that limits on interstate shipments are necessary to protect patients or prevent "manufacturing in the guise of compounding." The passage of compounded prescriptions across state borders affects neither patient care nor determines whether a compounding pharmacy is acting as a "manufacturer." The act of crossing a state line does not transform a compounded prescription into a manufactured drug.

The goal of Congress by including the option of the MOU was to encourage states to work with the FDA. The legislative alternative is acceptance of the 5 percent cap on interstate distribution provided in section 503A, which severely limits the options available to patients and pharmacists. A state that declines to enter into the MOU puts its pharmacists at a severe handicap. The legislative intent of the 5 percent limit was to be so confining as to virtually compel the states to enter the MOU. It is inappropriate for FDA to use the leverage provided by Congress to coerce states to enter into an MOU that fails to serve the needs of patients and forces the states to take on tasks that are not theirs.

It is the sincere hope that FDA will see the flaws in the MOU draft and discard it as currently written. SCmP member pharmacists urge the FDA to work with the National Association of Boards of Pharmacy as well as other interested pharmacy organizations to develop an appropriate MOU that ensures that patients' interests are served and Congress' objectives furthered.

Sincerely,

Gary McCrory, R.Ph.
Chairman
Texas Pharmacy Association
Section of Compounding Pharmacists

cc National Association of Boards of Pharmacy
International Academy of Compounding Pharmacists

TEXAS PHARMACY ASSOCIATION

DOCKETS MANAGEMENT BRANCH
FOOD AND DRUG ADMINISTRATION
(HFA-305), ROOM 1061
5630 FISHERS LN
RICKVILLE MD 20852

1624 East Anderson Lane, Austin, Texas 78752-4805 • P.O. Box 14709, Austin, Texas 78761-4709 • (512) 836-8300 • (800) 866-5403 • Fax: (512) 836-0308